

REMARKS

Claims 78, 98-115 and 119-126 are pending in the present application. Claims 1-77, 79-97; 116-118 and 127 have been canceled without prejudice or disclaimer. Claims 111-113 have been cancelled as being drawn to non-elected subject matter.

Applicants, by canceling or amending any claims, make no admission as to the validity of any rejection made by the Examiner against any such claims. Applicants reserve the right to reassert any of the claims canceled and/or the original claim scope of any claim amended, in a continuing application.

No new matter has been added

In view of the following, further and favorable consideration is respectfully requested.

I. At page 2 of the Official Action, claim 127 has been rejected under 35 USC § 112, first paragraph.

The Examiner asserts that claim 127 does not comply with the written description requirement of 35 USC § 112.

Applicants respectfully submit that the rejection of claim 127 has been rendered moot by the cancellation of the same. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

II. At page 2 of the Official Action, claims 78, 98-110, 115, 119-124 and 127 have been rejected under 35 USC § 112, first paragraph as failing to comply with the enablement requirement.

The Examiner asserts that the specification does not reasonably provide enablement for the freezing of any biological matter, particularly with no cryoprotectant.

In view of the following, the rejection of claims 78, 98-110, 115 and 119-124 is respectfully traversed.

In addition, Applicants note that the rejection of claim 127 has been rendered moot by the cancellation of the same. Accordingly, reconsideration and withdrawal of the rejection of claim 127 is respectfully requested.

With regard to claims 78, 98-110, 115 and 119-124, Applicants respectfully submit that the specification, figures, and examples, provide ample guidance to the skilled artisan in view of the state of the art at the time the application was filed, to make and use the claimed subject matter without undue experimentation.

Applicants once again note that the court in *In re Wright* held that nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. Applicants submit that the specification is replete with instances where methods, as claimed, are described that do not include a discussion of including a cryoprotectant. Thus, it is submitted that the specification clearly envisages, describes and enables a method of freezing a biological material selected from the group consisting of semen, blood, blood cells, blood constituents and umbilical cord blood, with or without a cryoprotectant, as claimed, without undue experimentation. For example, the Examiner is politely directed to page 6, lines 14-24 of the present specification, which is just one example where no cryoprotectant is mentioned or required. Taken with the previously submitted Declaration Under 37 CFR 1.132, which included Attachment A, it is submitted that a skilled artisan would be able to make and use the claimed subject matter without undue experimentation.

In view of the foregoing, Applicant submits that the specification enables the skilled artisan to make and use the full scope of claims 78, 98-110, 115 and 119-124 within the meaning of 35 USC § 112, first paragraph. Thus, reconsideration and withdrawal of this rejection is respectfully requested.

III. At page 7 of the Official Action, claims 78, 98-100, 102, 106, 114 and 123-127 have been rejected under 35 USC § 102(a) as being anticipated by Arav et al. (reference U, of record referred to hereinafter as “the Arav publication”) in view of the Baxter Catalog (reference V, of record).

The Examiner asserts that Arav publication anticipates the subject matter of claims 78, 98-100, 102, 106, 114, 123-127.

At the outset, Applicants submit that the rejection of claim 127 has been rendered moot by the cancellation of the same. Accordingly, reconsideration and withdrawal of the rejection of claim 127 is respectfully requested.

With regard to claims 78, 98-100, 102, 106, 114 and 123-126, Applicants once again respectfully submit that this rejection is moot since the Arav et al. publication is not proper prior art against the present claims within the meaning of 35 USC § 102(a). Regarding the Examiner's assertion at page 12, 1st paragraph of the Official Action that Uri Meir is the sole inventor of the presently claimed subject matter, Applicants respectfully direct the Examiner's attention to the Declaration and Official Filing Receipt for the present Application which clearly identify three inventors for all of the claims pending in the present application, i.e., Uri Meir, Amir Arav and Victor Rzepakovsky. Thus, the Examiner's assertion is without merit.

In addition, Applicants note that as admitted by the Examiner, the Arav et al. publication does not teach every element of the presently pending claims as required for anticipation under 35 USC § 102. In this regard, Applicants note that the discussion of another reference, i.e., US Patent No. 5,873,254, in a literature publication, does not incorporate the disclosure of the additional reference into the literature publication being cited against claims. Thus, should the Examiner wish to maintain this rejection, Applicants request clarification of where all of the elements are taught in the Arav publication, without reliance on two additional references.

In view of the foregoing, Applicants submit that the Arav publication does not teach each and every element of the claimed subject matter, either expressly or inherently. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

IV. At page 7 of the Official Action, claims 78, and 98-110, 114, 115 and 119-127 have been rejected under 35 USC § 103 (a) as being unpatentable over US Patent No. 5,873,254 (the '254 patent), both alone and in combination with US Patent No. 4,131,200 (the '200 patent) in view of Dayian et al. (reference V2 of record).

The Examiner asserts that although the '254 patent does not describe the size of the sample as presently claimed, the generic description in the Summary of the '254 patent is not limited with regard to the size of the sample. With regard to combination of the '254 patent with the '200 patent and Dayian et al., the Examiner asserts that the substitution of the controlled freezing method described in the '254 patent for the uncontrolled platelet freezing method described in the '200 patent would have been obvious to a person of ordinary skill in the art.

In view of the following, the rejection of claims 78, and 98-110, 114, 115 and 119-126 is respectfully traversed.

In addition, Applicants note that the rejection of claim 127 has been rendered moot by the cancellation of the same. Accordingly, reconsideration and withdrawal of the rejection of claim 127 is respectfully requested.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), “a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” (*KSR*, 550 U.S. 398 at 417.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the

limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Applicants can rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed range. "The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . . In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2114.05(III).

It is submitted that a proper case of *prima facie* obviousness has not been established because all the elements of the presently claimed subject matter are neither taught nor suggested by the '254 patent, '200 patent or Dayian et al., whether taken alone or in combination. In addition, Applicants submit that even if a case of *prima facie* obviousness were established, a *prima facie* of obviousness would be rebutted because the presently claimed subject matter exhibits unexpectedly superior results in as much as the presently claimed subject matter provides for freezing of large samples, where the sample size is critical.

From the outset, Applicants respectfully submit that the presently claimed subject matter is directed to methods of freezing large samples of biological matter selected from the group consisting of semen, blood, blood cells, blood constituents and umbilical cord blood, which is in the form of a sample having a minimal dimension in each of two mutually perpendicular cross-sections exceeds 0.5 centimeters. In contrast, none of the '254 patent, the '200 patent or Dayian et al. teach or suggest the presently claimed methods,

namely the changing the temperature presently claimed sample size as recited in the present claims.

However, assuming *arguendo* that the '254 patent, the '200 patent or Dayian et al. did teach or suggest every element of the presently claimed subject matter, Applicants respectfully submit that the presently claimed subject matter results in the unexpectedly superior results of making it possible to freeze and thaw viable biological matter in the presently claimed sample size.

In view of the remarks set forth herein, it is submitted that, whether taken alone or in combination none of the cited references render the presently claimed subject matter obvious within the meaning of 35 USC § 103 (a). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

V. At page 10 of the Official Action, claims 78, and 98-110, 114, 115 and 119-123 have been rejected under 35 USC § 103 (a) as being unpatentable over the Arav publication in combination with the '254 patent in light of Swanson et al. (reference W of record) and the Baxter catalog.

The Examiner asserts that the cited references render the claimed subject matter obvious for the reasons set forth in the Official Action

In view of the following, this rejection is respectfully traversed.

Applicants respectfully submit that this rejection is moot because the Arav publication is not prior art against the presently claimed subject matter. In addition, since the remaining references do not teach or suggest every element of the claimed subject matter, the presently pending claims are not *prima facie* obvious. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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